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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,161	05/31/2001	Wilson O. Endege	1657/1014B	8065

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/871,161

Applicant(s)

ENDEGE ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, 8, 10, 12, 13, 15, 27, 29 and 30, drawn to an isolated nucleic acid, vector, host cell and probe/primer, classified in class 536, subclasses 23.1 and 24.3 and class 435, subclasses 320.1, 325 and 252.3. If this Group is elected, then the below summarized sequence election is required.
 - II. Claim 7, drawn to a transgenic animal, classified in class 800, subclass 8. If this Group is elected, then the below summarized sequence election is required.
 - III. Claims 9 and 28, drawn to a polypeptide and pharmaceutical composition, classified in classes 530 and 514, subclasses 350 and 1, respectively. If this Group is elected, then the below summarized sequence election is required.
 - IV. Claim 11, drawn to an array, classified in class 435, subclass 287.2. If this Group is elected, then the below summarized sequence election is required.
 - V. Claim 14, drawn to an antibody, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is required.
 - VI. Claims 16-21, drawn to a kit and method for determining the phenotype of a cell comprising a probe/primer or protein, classified in class 422, subclass 61 and class 435, subclasses 6 and 7.1. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized specie election is also required.

Art Unit: 1631

- VII. Claim 22, drawn to a method for determining the presence or absence of a nucleic acid, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.
- VIII. Claim 23, drawn to a method for determining the presence or absence of a polypeptide, classified in 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.
- IX. Claim 24, drawn to a method for detecting a mutation in a test nucleic acid, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.
- X. Claims 25 and 26, drawn to a method for identifying an agent, which alters the level of expression in a cell, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.
- XI. Claims 31 and 32, drawn to a method for detecting cancer, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.
- XII. Claims 33 and 34, drawn to a method for detecting cancer in a patient sample in which an antibody to a protein is used, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.

SPECIE ELECTION REQUIREMENT FOR GROUPS VI:

- 2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: Direct nucleic acid quantitation.

Art Unit: 1631

Species B: Direct protein quantitation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 18 and 20 of Group VI are generic. These species are distinct critical limitations for differential gene expression, which may be analyzed via hybridization assays or via protein analysis assays. Species of protein or nucleic quantitation are generally separately analyzed and published, and thus document the undue search burden if searched together.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). Specific to Group IV, the claims in this Group are directed to a combination, which is at least a plurality of nucleic acid sequences. Applicant may elect two sequences if Group IV is elected. It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

2. The inventions of Groups [I, VI (nucleic acid), VII, IX, X, XI], II, [III, VI (protein), VIII, XII], IV and V are distinct inventions because they are directed to different chemical types or methods regarding the critical limitations therein. For Groups I, VI (nucleic acid), VII, IX, X

Art Unit: 1631

and XI the critical feature is a nucleic acid. For Group II, the critical feature is a transgenic animal. For Groups III, VI (protein), VIII, XII, the critical feature is a polypeptide. For Group IV, the critical feature is an array. For Group V, the critical feature is an antibody. Further, it is acknowledged that various processing steps may cause a polypeptide, transgenic animal, array and antibody of Groups II-V to be directed as to its synthesis by a nucleic acid set forth in Group I, however, the completely distinct critical features of each Group of the inventions of nucleic acid, transgenic animal, array, and antibodies support the undue search burden if they were examined together. Additionally, nucleic acid, transgenic animal, array and antibodies and their methods of use have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately.

3. Inventions in Groups I, VI (nucleic acid), VII, IX, X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of Novel human genes and gene expression products:II, the nucleic acid molecule of Group I may be utilized in the distinct usages as in Group VI (nucleic acid), a kit and method for determining the phenotype of a cell comprising a probe/primer. As needed in Group VII, a method for determining the presence or absence of a nucleic acid. As needed in Group IX, detecting a mutation in a test nucleic acid. As needed in Group X, a method for identifying an agent, which alters the level of expression in a cell. As need in Group XI, a method for detecting cancer, or alternatively, as an antisense

therapy. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

4. Inventions in Groups III, VI (protein), VIII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of Novel human genes and gene expression products:II, the amino acid of Group III may be utilized in the distinct usages as needed in Group VI (protein), a method and test kit for determining the phenotype of transformed cells, comprising an antibody specific for a protein. As needed in Group VIII, a method for determining the presence or absence of a polypeptide. As needed in Group XII, a method for detecting a cancer in a patient sample in which an antibody to a protein is used, or alternatively, a polypeptide may be used in a method for determining the degree of affinity between a ligand and its respective receptor in competitive binding assays, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.


Art Unit: 1631

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
8. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Art Unit: 1631

11. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
1/29/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER